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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,490	01/08/2001	Michael T.K. Ling	1417Y P 407	4232
75	90 07/31/2003			
Mark J. Buonaiuto, Esq.			EXAMINER	
Assistant Gener Baxter Internati	• •		NOLAN, SA	ANDRA M
One Baxter Parkway, DF2-2E			ART UNIT	PAPER NUMBER
Deerfield, IL 6	00015		1772	
			DATE MAILED: 07/31/2003	i

Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)					
		09/756,490	LING ET AL.					
Office Action Summary		Examiner	Art Unit					
		Sandra M. Nolan	1772					
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover sheet with the o	correspondence address					
A SH THE I	ORTENED STATUTORY PERIOD FOR REPL	_	•					
after - If the - If NC - Failu - Any r	nsions of time may be available under the provisions of 37 CFR 1.1 SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period re to reply within the set or extended period for reply will, by statute eply received by the Office later than three months after the mailing patent term adjustment. See 37 CFR 1.704(b).	ly within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	rs will be considered timely. the mailing date of this communicatio (35 U.S.C. § 133).	n.				
Status								
1)⊠	Responsive to communication(s) filed on <u>02</u>		•					
2a)⊠	,—	nis action is non-final.						
3)□ Dispositi	Since this application is in condition for allow closed in accordance with the practice under on of Claims			is				
•	Claim(s) 1-111 is/are pending in the application	nn	·					
•	4a) Of the above claim(s) <u>6-10 and 17-111</u> is/are withdrawn from consideration.							
	Claim(s) is/are allowed.							
·	Claim(s) <u>1-5 and 11-16</u> is/are rejected.							
-	Claim(s) is/are objected to.							
·	Claim(s) are subject to restriction and/o	or election requirement.	•					
•	on Papers							
9)[The specification is objected to by the Examine	er.						
10)[The drawing(s) filed on is/are: a)☐ acce	pted or b)⊡ objected to by the Exa	miner.					
•	Applicant may not request that any objection to the	e drawing(s) be held in abeyance. S	ee 37 CFR 1.85(a).					
11) 🔲 .	The proposed drawing correction filed on	_ is: a)□ approved b)□ disappro	oved by the Examiner.					
	If approved, corrected drawings are required in re	ply to this Office action.						
12)	The oath or declaration is objected to by the Ex	caminer.						
Priority u	ınder 35 U.S.C. §§ 119 and 120		·					
13)	Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(a	a)-(d) or (f).					
a)[☐ All b)☐ Some * c)☐ None of:							
	1. Certified copies of the priority document	s have been received.						
	2. Certified copies of the priority document	ts have been received in Applicati	ion No					
* S	3. Copies of the certified copies of the prio application from the International Bu See the attached detailed Office action for a list	reau (PCT Rule 17.2(a)).		·				
14) 🗌 A	acknowledgment is made of a claim for domest	ic priority under 35 U.S.C. § 119(e) (to a provisional applicat	ion).				
) The translation of the foreign language pro Acknowledgment is made of a claim for domest							
Attachmen	· ·		·	2				
2) Notic	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1</u>	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)					
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DETAILED ACTION

Election/Restrictions

- 1. This application contains claims 6-10 and 17-111 drawn to an invention nonelected with traverse in Paper Nos. 7 and 10 (the responses dated 23 October 2003 and 06 February 2003, respectively).
- 2. A complete reply to this final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
- 3. The examiner notes applicants' remarks concerning the elections of species "e" and "m" in Paper No. 7. However, as was stated in the office action dated 26 February 2003 (Paper No. 11), the elections were not accompanied by a list of all claims readable on the elected species, so the species election was incomplete.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 23 June 2003 (Paper No. 13) was considered by the examiner.

Rejections Withdrawn

- 5. The 35 USC 112 rejection of claims 2-4 as indefinite, as set out in section 8 of Paper No. 11, is withdrawn in view of applicants' amendments in the response dated 02 June 2003 (Paper No. 12).
- 6. The 35 USC 102 rejection of claims 1-4, 11 and 15 as anticipated by Heilmann et al (US 5,928,744), as stated in section 10 of Paper No. 11, is withdrawn in view of the amendments in Paper No. 12.

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7. The 35 USC 103 rejection of claims 1-5 and 11-16 as unpatentable over Mueller (EPO 0564231 B1) in view of Heilmann and Ahmed et al (US 6,184,290), as expressed in section 13 of Paper No. 11, is withdrawn in view of the amendments in Paper No. 12.

New Rejections

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 10. Claims 1-5, 11, 13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbaum et al (WO 95/13918).

Rosenbaum teaches multilayer structures for use with medical solutions or blood products, such as bags and related items (page 5, lines 6-11). Its structures replace ones based on plasticized PVC (page 4, lines 25-27). It structures contain a skin layer of polypropylene (PP) blended with a SEBS copolymer (page 5, line 35 through page 6, line 2). It also contains a radio-frequency (RF) susceptible layer (page 6, lines 3-9).

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The RF susceptible layer contains propylene in homopolymers or random copolymers with ethylene (page 10, lines 9-13), ethylene/butene copolymer (page 10, line 21), a C₂₋₁₃ diamine/dimer fatty acid-based polyamide (page 11, lines 26-32), and a SEBS block copolymer (page 12, lines 9-14).

Rosenbaum fails to recite tubing or the use of single site catalysis to make its ethylene-olefin copolymers.

Single site catalysts are well known catalysts for making olefin copolymers.

In the absence of convincing objective evidence to the contrary, it would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the multilayer structures of Rosenbaum to make various medical items, such as tubing, for use with medical solutions or blood.

In the absence of convincing objective to the contrary, it would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ single site catalysts to make the olefin copolymers used in the structures of Rosenbaum.

11. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenbaum as applied to claims 1-5, 11, 13 and 15-16 above, and further in view of Nicola et al (US 6.004,636).

Rosenbaum is discussed above. It fails to teach the use of multiple SEBS polymers or SEBS triblocks.

Nicola teaches medical bags made using PP matrix polymers blended with SENS phase polymers (col. 2, lines 27-47). In claim 4 of the patent (col.4, lines 5-13), it

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says that the matrix system may contain blends of SEBS triblocks with mixtures of SEBS triblocks and SEB copolymers. The bags can be used immediately after heat sterilization (col. 1, lines 53-55).

Rosenbaum and Nicola are analogous because they both deal with medical items containing SEBS and PP in one or more layers.

It would have been obvious to one having ordinary skill in the art at the time that the invention was made to employ the PP/SEBS combinations of Nicola in the tubing suggested by Rosenbaum in order to produce tubing that could be used immediately after sterilization.

It is deemed desirable to make tubing that can be used immediately after sterilization in order to minimize the handling required before the tubing is used.

Final Rejection

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication should be directed to the Examiner, Sandra M. Nolan, whose telephone number is 703/308-9545. The Examiner can normally be reached on Monday through Thursday, from 6:30 am to 4:00 pm, Eastern Time.

If attempts to reach the Examiner by telephone are unsuccessful, her supervisor, Harold Pyon, can be reached at 703/308-4251. The general fax number for the art unit is 703/305-5436. The fax number for after final communications is 703/872-9310. The receptionist answers 703/308-0661.

S. M. Nolan

Patent Examiner

Technology Center 1700

SMN/smn 09756490(14) 28 July 2003